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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,879	04/16/2007	Karl-Hermann Schlingensiepen	074060.6	2382

27805 7590 02/17/2010

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EXAMINER	
GIBBS, TERRA C	

ART UNIT	PAPER NUMBER
1635	

MAIL DATE	DELIVERY MODE
02/17/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/567,879	SCHLINGENSIEPEN ET AL.	
	Examiner	Art Unit	
	TERRA C. GIBBS	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 December 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-5,7-11 and 14-16* is/are allowed.

6)☒ Claim(s) *6,12 and 13* is/are rejected.

7)☒ Claim(s) *12 and 17* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is a response to Applicant's Amendment and Remarks filed December 9, 2009.

Claim 1 has been amended.

Claims 1-17 are pending in the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

In the previous Office Action mailed August 11, 2009, claims 1, 4-6, 8-11, and 15-17 were rejected under 35 U.S.C. 102(b) as being anticipated by WO 99/65928 A2. **This rejection is withdrawn** in view of Applicant's Amendment filed December 9, 2009. Specifically, the Examiner is withdrawing this rejection in view of Applicant's Amendment to claim 1 to recite: An antisense oligonucleotide selected from the group consisting of the sequence 5' - TTG CAT AAA CCC AAG GAG – 3' (SEQ ID NO:1) and modification thereof, and fragments consisting of subsequences of SEQ ID NO:1 of at least 8 nucleotides and modifications thereof. It is noted that this Amendment adds new claim language which renders the claim close ended and therefore, the prior art of WO 99/65928 A2 is no longer applicable to the instant claims.

In the previous Office Action mailed August 11, 2009, claims claims 1, 5, 6, 8, and 15-17 were rejected under 35 U.S.C. 102(b) as being anticipated by WO 01/77384

A2. **This rejection is withdrawn** in view of Applicant's Amendment filed December 9, 2009. Specifically, the Examiner is withdrawing this rejection in view of Applicant's Amendment to claim 1 to recite: An antisense oligonucleotide selected from the group consisting of the sequence 5' - TTG CAT AAA CCC AAG GAG – 3' (SEQ ID NO:1) and modification thereof, and fragments consisting of subsequences of SEQ ID NO:1 of at least 8 nucleotides and modifications thereof. It is noted that this Amendment adds new claim language which renders the claim close ended and therefore, the prior art of WO 01/77384 A2 is no longer applicable to the instant claims.

Claim Rejections - 35 USC § 103

In the previous Office Action mailed August 11, 2009, claims 1-3 were rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/65928 A2 (Reference A.M on Applicant's Information Disclosure Statement filed February 9, 2006) in view of WO 01/68122 (Reference A.L on Applicant's Information Disclosure Statement filed February 9, 2006). **This rejection is withdrawn** in view of Applicant's Amendment filed December 9, 2009. Specifically, the Examiner is withdrawing this rejection in view of Applicant's Amendment to claim 1 to recite: An antisense oligonucleotide selected from the group consisting of the sequence 5' - TTG CAT AAA CCC AAG GAG – 3' (SEQ ID NO:1) and modification thereof, and fragments consisting of subsequences of SEQ ID NO:1 of at least 8 nucleotides and modifications thereof. It is noted that this Amendment adds new claim language which renders the claim close ended and therefore, the prior art of WO 99/65928 A2 is no longer applicable to the instant claims.

Rejoinder in light of In re Ochiai

Claims 1-5, 8-11, 15, and 16 are allowable. In light of *In re Ochiai*, method claims 7 and 12-14 will be rejoined and examined with the elected invention of composition claims 1-5, 8-11, 15, and 16.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12 and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is a scope enablement rejection.

Claims 12 and 13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method comprising providing the pharmaceutical composition according to claim 1 in a method for the **treatment** of at least one of neoplasms, infections, or immunosuppressive disorders, does not reasonably provide enablement for a method comprising providing the pharmaceutical composition according to claim 1 in a method for the **prevention** of at least one of neoplasms, infections, or immunosuppressive disorders. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly

connected, to make and/or the invention commensurate in scope with these claims.

The claimed invention is a class of invention which the CAFC has characterized as "the unpredictable arts such as chemistry and biology." Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d 1316, 1330 (Fed. Cir. 2001).

In regards to a method comprising providing the pharmaceutical composition according to claim 1 in a method for the **prevention** of at least one of neoplasms, infections, or immunosuppressive disorders, the Applicant has not shown that neoplasms, infections, or immunosuppressive disorders could be prevented. In addition, the Applicant does not disclose how pharmaceutical composition according to claim 1 is to be used in order to *prevent* neoplasms, infections, or immunosuppressive disorders. It is not clear from the specification, that in order for prevention of neoplasms, infections, or immunosuppressive disorders, whether the patient is potentially prone for neoplasms, infections, or immunosuppressive disorders or whether a recurrence is being prevented. Is the therapy to prevent recited here started months ahead or days ahead of a probable expectation of neoplasms, infections, or immunosuppressive disorders? Is there a particular amount of the pharmaceutical composition according to claim 1 formulation that needs to be administered? Is a particular treatment regimen necessary? How long must such a treatment continue in order to prevent neoplasms, infections, or immunosuppressive disorders? Without specific guidance from the specification, one is left with undue trial and error experimentation to practice the instant invention.

Further, neither Applicant nor the prior art has exemplified that one of skill in the

art would expect that the incidence of neoplasms, infections, or immunosuppressive disorders could be prevented. For example, Applicants show that SEQ ID NO:1 exhibited the strongest inhibition of MIA expression in melanoma cells in culture, when compared to other MIA antisense oligonucleotides known in the prior art (see Figure 1). The prior art teaches that antagonizing MIA activity using antisense techniques may represent a novel therapeutic strategy for treatment of malignant melanomas. See Jachimczak et al. (Int. J. Cancer, 2005, Vol.113:88-92).

In view of the lack of guidance and working examples provided in the specification as filed, the level of unpredictability in the art in regards to using the pharmaceutical composition according to claim 1 to prevent neoplasms, infections, or immunosuppressive disorders, and the breadth of the given claims, it is concluded that undue experimentation would be required to practice the invention throughout the full scope of the claims, and therefore the invention is not fully enabled.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 is indefinite because the claim incorrectly recites, "$(B\text{-}p\text{-}B\text{-}P)_n$", instead of "$(B\text{-}p\text{-}B\text{-}p)_n$". Because "$(B\text{-}p\text{-}B\text{-}P)_n$", is incorrectly recited in the claim, one of ordinary

skill in the art would not be reasonably apprised of the metes and bounds of such a term. Appropriate correction is required.

Claim 13 is indefinite because the term "MIA" is not clearly defined. Since abbreviations often have more than one meaning, it is suggested that inserting the full name, "melanoma inhibitory activity" would overcome the instant rejection.

Claim Objections

Claim 12 is objected to because of the following informalities: Claim 12 is grammatically incorrect since the claim recites, "A method comprising providing The use of the pharmaceutical composition according to claim 1". Appropriate correction is required.

Claim 17 is objected to as being dependent upon a rejected based claim, but would be allowable if rewritten in independent form including all of the limitations of the base claims and any intervening claims.

Conclusion

Claims 1-5, 7-11, and 14-16 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is 571-272-0758. The examiner can normally be reached from 9 am - 5 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Tracy Vivlemore can be reached on 571-272-2914. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Terra Cotta Gibbs/
February 10, 2010